Public Health Association of Australia submission on the Review of the National Gene Technology Regulatory Scheme Phase 2 Consultations

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Introduction

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups, the Association's journal, the Australian and New Zealand Journal of Public Health (ANZJPH), draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

In recent years, PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

Vision for a healthy population

The PHAA has a vision for a healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and healthy environment, improving and promoting health for all.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Preamble

PHAA welcomes the opportunity to provide input to the Review of the National Gene Technology Scheme – Phase 2 consultations.

The PHAA notes that Phase 2 of the Consultation asks for replies to 52 questions that have been posed in its on-line submission process (https://consultations.health.gov.au/best-practice-regulation/review-of-national-gene-technology-scheme/consultation/) and that the Consultation does not require the PHAA to answer all of the questions.

This submission is based on PHAA's policy on Genetically Modified Foods, which can be seen at https://www.phaa.net.au/documents/item/1700. The PHAA has had a policy on GM foods since 1999. The policy has been revised and re-endorsed five times, most recently in 2016.

The policy has been informed by the training and experience of the members of the PHAA, which includes experts in food, nutrition, disease control, epidemiology, toxicology, medicine, and medical research. The PHAA has a Food and Nutrition Special Interest Group.

There are several items in the policy that are relevant to the topic of this submission.

First, the PHAA regards organisms developed using the new technologies described in the Background Paper of the 2017 Review of the National Gene Technology Regulatory Scheme as GMOs. Specifically, PHAA's policy on Genetically Modified Foods includes the following paragraph in its description of GMOs. "New techniques include crops designed to produce a new RNA molecule rather than a new protein,[1] and new gene editing techniques (e.g. CRISPR) that can also be used as a "gene drive" to spread altered DNA rapidly through a population and for developing synthetic biology.[2]"

Furthermore, the PHAA considers that GMOs should be regulated and that a GMO cannot be considered to be safe until there is independent, peer-reviewed evidence that it is safe. Assumptions of safety should never be used. It should be noted that various members of the PHAA have been, and continue to be, involved in investigations into claims of safety of e.g. tobacco, alcohol, pharmaceutical drugs, food-related substances, environmental toxins etc. and are aware that industry-related claims of safety are often overturned once independent laboratory, clinical and epidemiological research has been undertaken. As a result, members have learnt to be wary of claims of safety by vested interests and to require evidence to support such claims.

Not only does the PHAA have members who undertake epidemiological studies, but it also has members who "pick-up the pieces", such as clinicians, once evidence of harm has been found. Consequently, the PHAA is well aware of the huge human and social costs that can accrue when things go wrong because an incorrect assumption was made that something was safe; or incomplete, or insufficient information was given by vested interests to regulators and the public.

As a result, PHAA's policy on GM food states:

- Food regulation should aim to protect public health and provide information to consumers.
- The precautionary principle should be applied to GMOs.
- Most safety assessments on GM crops are done by people associated with the GM industry and there are relatively few independent assessments[3], particularly when a new GM crop is submitted to Food Standards Australia New Zealand (FSANZ). FSANZ does not require animal feeding studies to assess safety.[4] Industry animal studies usually involve short-term toxicology studies of a few days and do not measure allergic, reproductive or cancer outcomes. Any longer studies tend to use farm animals (e.g. chickens) that are not physiologically comparable to humans and measure outcomes that are not measures of human health (e.g. meat and milk production)[5]. Reviews of the latter studies tend to find little adverse effects, while some reviews of raw industry data[6] and independent toxicology studies have found adverse effects.[7]
- Regulators should use thorough, independent experimental evidence in assessments rather than assumptions. GM foods should not be considered safe until they have undergone long-term animal safety assessments utilizing endpoints relevant to human health and conducted by independent researchers.

- A comprehensive monitoring and surveillance system should be instigated to track the effects of GM foods.
- The labelling system should be improved to include all ingredients (including refined) originating from GM organisms (including micro-organisms), and from animals fed GM feed.
- Labelling laws should be policed.
- Australian governments should impose a freeze on importing GM foods, growing GM crops commercially and patenting genetic resources for food until thorough independent research into their effects is undertaken.
- The PHAA will advocate for publicly funded, independent research into the effects of GM crops, and for GMOs being made freely available to any researcher researching agronomic, environmental or health aspects of GM crops.
- The PHAA will advocate for a strong public health presence in the staff, advisory committees and Boards of the APVMA, OGTR and FSANZ to improve safety assessment procedures

PHAA Response to the 2017 Review of the National Gene Technology Regulatory Scheme Consultation Paper

Theme 1 – Technical issues

What technological advances can be foreseen that might pose regulatory challenges for the Scheme?

The Review of the National Gene Technology Scheme 2017 Consultation Paper has mentioned many of the main technological changes that can be foreseen in the near future. These include CRISPR, TALENS, ZFN, oligonucleotide directed mutagenesis, cisgenesis, synthetic biology, human germline gene therapy and gene drives. However, little mention has been made of trans-grafting, RNA-dependent DNA methylation and dsRNA technology, which will also likely pose regulatory challenges for the scheme.

What are the potential impacts of the capability to make small edits in the DNA of an organism using no foreign DNA?

The potential impacts can be huge. For example, in medicine, it is understood that even tiny changes in the DNA of a person can have such serious effects that the person dies. In two of many examples, the most common genetic mutation causing cystic fibrosis (a disease of the lungs resulting in premature death) is a deletion of three nucleotides in the genome[8], while Tay-Sachs disease (a disease that destroys nerve cells in the brain and spinal cord, usually resulting in death in early childhood) can result from a single base deletion or insertion in the genome[9]. Note that the presence of foreign DNA was not required in order to make the change dangerous. The DNA change itself was dangerous. While the examples given are for homo sapiens, the potential to cause serious problems in other species holds.

Such small edits can result in toxic products being unexpectedly produced and therefore all organisms made using small edits should be fully regulated and fully safety assessed before they enter the environment.

It should also be noted that small edits made repeatedly can result in producing an organism that is substantially different to the starting organism.

The PHAA regards organisms developed using the new technologies described in the Background Paper of the 2017 Review of the National Gene Technology Regulatory Scheme, including these small edits, as GMOs. The PHAA further considers that they should be regulated.

Under what circumstances might it be practical, efficient or appropriate to regulate gene editing under the GT Act when, from an enforcement perspective, it may not be possible to distinguish the products of gene editing form the products of conventional methods?

A view is often expressed by proponents of GMOs that organisms developed using new GM techniques should not be regulated because they cannot be detected. Three things should be noted about this view.

The first is that detection techniques for these new organisms are currently available using omics techniques such as transcriptomics, proteomics and metabolomics. And, as these techniques improve over time, their ability to detect these new organisms will improve. The current and potential future uses of these techniques for detection is discussed at length in Chapter 7 of the National Academies of Science report of 2016[10]. That report concluded that these techniques could play an important role in the regulation of crops developed using these new techniques.

It should also not be assumed that omics methods will be the only methods of detection available in the future.

The second is that it is highly unlikely that a patented organism would be released by a company or organisation for sale without some means of protecting their intellectual property (IP) rights over that organism. After all, there is little point in spending large amounts of time and money on developing a new GMO if developers cannot recoup their investment money and make a profit from the sale of their product. It is therefore logical that the developer will have a means of genetically ”branding” a GMO to ensure that it is not used without a licence, i.e. so that it can be legally proven that a particular GM organism belongs to a particular company so that payment can be enforced for any use of that GMO. Furthermore, regulators can require developers to provide a test to detect any GMO produced. It is recommended that this occur.

The third is that difficulty with compliance has not prevented Commonwealth and State Governments and the judiciary from enacting compliance procedures elsewhere.

The emerging applications, and their definitional implications for research purposes, are another area the Review will consider. Do these applications of gene technologies present unique issues for consideration? If so, how might these issues be best addressed by the Scheme?

In The Review of the National Gene Technology Scheme 2017 Consultation Paper, emerging applications are listed as: synthetic biology, human germline gene therapy and gene drives. These are only a few of the new techniques emerging. Others include CRISPR, TALENS, ZFN, oligonucleotide directed mutagenesis, cisgenesis, trans-grafting, RNA-dependent DNA methylation and dsRNA technology. Given the rate of change in the area, other technologies are likely to emerge from laboratories in the near future. Each technique has a different risk and benefit profile. In addition, a given technique applied to a different species will have a different risk and benefit profile. For example, a gene drive applied to a plant is likely to have a different risk profile to a gene drive applied to a bacterium or a fly or a toad or a rat or a fish or a bird, since different species move through the environment in different ways and spread their genes through their populations in different ways. Given this complexity, there is a need for specialist oversight to regulate each new technology on a case-by-case basis to determine the potential risks and benefits of each. There is therefore a need for these new techniques to be regulated.

Advocates for deregulating the use of these new techniques in areas such as agriculture ignore the fact that it is well understood that when these new techniques are used in medicine, they can result in unexpected and unprecedented genetic modifications. Because of this, these new techniques are heavily regulated for medical applications. To regulate these new techniques in medicine but to deregulate them in areas such as agriculture would be policy double-speak. That is, apparently the techniques are so precise, predictable and safe that they do not need regulation, while at the same time being so imprecise, unpredictable and unsafe that they do require regulation.

Further reasons for undertaking a safety assessment of all GMOs are: (1) there seems to be uncertainty and debate about how these new techniques actually work, even amongst genetic engineers and risks cannot be adequately determined without a full and proper understanding of the techniques; (2) these new techniques are in their infancy and are constantly changing as techniques evolve, so that an understanding of the techniques used today may not provide an understanding of the techniques used tomorrow; and (3) safety assessments of organisms made using these new techniques take time and therefore lag behind the development of the techniques themselves. Consequently, any decision now that they are safe would be scientifically unsound and deregulating something that is not known to be safe would be unwise. To conclude that products of the new genetic techniques do not require regulation is to effectively decide, *ipso facto*, that every product of the new techniques is safe, before an adequate safety assessment is done on **any** product of the new techniques to determine if **any** product is safe. This could be considered to be a contravention of the Object of the Gene Technology Act.

> **The Review is seeking further input on the prospect of the intentional release of a GMO or organism with changed characteristics, delivered by one of the new breeding technologies, into the environment. What are the potential implications of a release of a GMO targeting an invasive species in Australia?**

The potential implications depend on the nature of the GMO being suggested for release, how it acts on the invasive species, such as whether the GMO acts as a gene drive, how numerous the invasive species is in the environment, what the impact on human health and the environment is likely to be, and how easy it would be to prevent the GMO from escaping the country.

For example, the imminent release of the non-GM herpes virus into Australia by the CSIRO to control carp in Australia's waterways has taken years of planning, including how to manage millions of dead and decomposing fish in Australia's waterways, and how to avoid a "blackwater event", potentially thousands of kilometres long, where so much oxygen is removed from the water from dying fish that most other fish in the system die[11]. Consequently, each potential release of an organism to control invasive species, whether GMO or not, needs to undergo a human and environmental health risk assessment by a regulator.

However, there are even greater risks to consider from a released GMO. The risks of gene-drive organisms are particularly worrying, because these organisms are designed to push a genetic change throughout the "natural", non-GM population of those organisms, thereby potentially extinguishing the "wild-type" organism. Consequently, extra care should be taken with these organisms, particularly as Australia has many examples of organisms spreading widely, regardless as to whether they were intentionally released (e.g. lantana, cane toads, rabbits) or unintentionally released (e.g. fire ants).

Care is also needed because an organism that may be a pest in one country may be indigenous to another and an important contributor to the ecosystem there. For example, rabbits are a pest in Australia and cause considerable damage to farms and ecosystems here, but they are indigenous to much of Europe. If a gene drive to kill rabbits escaped from a laboratory in Australia to infect rabbits here and was then accidentally or purposely introduced into Europe, it could cause major ecological damage there.

Any suggestions that gene-drive organisms could be easily contained, particularly once released into the environment in any way, should be regarded with considerable caution.

It is therefore recommended that any GMO designed to target an invasive species be fully regulated, particularly gene-drive organisms. It may in fact be wise to have a moratorium on gene-drive research in Australia. In support of this, it should be noted that the Broad Institute of MIT and Harvard prohibits the use of their CRISPR technology for gene drives in agriculture[12].

What are the technical issues to consider in the scenario of a GMO used to target an introduced plant, vertebrate or invertebrate pest?

Please see above.

Theme 2 – regulatory issues

What do you think is the most appropriate regulatory trigger for Australia in light of extensions and advancements in gene technologies?

Australia currently has a process trigger whereby an organism that is determined to be a GMO is subject to regulation. Proponents of quickly commercialising new GM techniques have been arguing for a product trigger for regulation, which would change the regulatory system to instead focus on the intended outcome of the change to the genome only and would ignore any risks inherent in the genetic modification process that was used, any risks in the spread of the GMO after commercial release into the environment, any economic risks to the Australian economy, and any risks to health and the environment. Because the developer of a GMO then will not have to undertake safety and other assessments before commercial release, the developer will benefit financially by reducing costs. However, the new techniques can result in unexpected off-target effects, including the production of toxic substances being unexpectedly produced. Consequently, the lack of safety studies prior to release would increase the probability of a toxic GMO being released into the environment and/or for human consumption. In addition, the associated lack of labelling and monitoring would make it harder to undertake epidemiological and other studies to determine if the GMO has harmed health or the environment. It would shift the focus onto "proof of harm", whereby those harmed by the GMO would need to prove that the GMO had harmed them, rather than preventing harm in the first place.

A product trigger could also result in many of the currently-regulated GMOs becoming deregulated. For example, the GM industry could argue that because plants can develop resistance to a given herbicide (e.g. Roundup) without the need for genetic modification, then crops genetically modified to be resistant to the herbicide should be deregulated, because the product is the same: the plant is tolerant to a herbicide. As most of the GM crops world-wide are designed to be herbicide tolerant, this could result in most GM crops grown elsewhere in the world being allowed to grow in Australia without any regulatory permission or oversight.

Consequently, Australia should retain a process trigger for regulating GMOs.

What factors need to be taken into account in the design of a product-based or a hybrid process/product regulatory scheme?

A product-based or a hybrid system should not be used. Please see above for the reasons why.

Phase 1 consultations identified a number of functional efficiencies that could be applied to the Scheme. The Review is exploring these issues from perspective of the existing process-based regulatory scheme. Are there any 'fixes' the scheme needs right now to remain effective?

Yes. The Scheme is very poor at measuring risk to health. Please see the answer to: "What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?", below, for more information. Please also see the answer to: "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below, for more information.

How would you streamline the existing scheme?

The concept of "streamlining" suggests a process involving reducing regulation. PHAA's policy calls for GMOs to be regulated, regardless of whether they are old or new techniques, on the basis that public health is more important than deregulation or "streamlining". Included in this, any truncating of timelines for certain decisions could put pressure on a regulator to undertake a risk assessment of a GMO within a shorter time, which may reduce the thoroughness of their work in assessing risk.

What other efficiencies could be gained through adjusting the interface between the Scheme and other regulators?

Various agencies may define gene technology differently. The definition of gene technology as given in the current Gene Technology Act should be used by all relevant regulators.

The Review is exploring whether greater alignment of regulation with risks should be further developed for environmental releases. What support exists for a regulatory framework providing for tiered risk?

According to the Review of the National Technology Scheme's Consultation Paper, tiering is being proposed for any plant which is destined to be turned into a GMO, to have a lower risk assessment applied to it if the plant has been highly characterised, regardless of the process used to turn the plant into a GMO.

There are several problems to the concept of tiering that are scientifically unjustified.

First, it ignores the different risk profiles of the different techniques used to make a GMO. One of the most studied genomes is the human genome. In medicine, these new GM techniques are recognised as producing unprecedented on-target and off-target genetic modifications that require careful regulatory oversight, even though the human genome is well characterised.

Second, the plants that have been highly characterised tend to be food plants, particularly cereal crops that enter the human food supply. Consequently, this move could result in reducing regulation and risk assessment for the very plants that are most likely to cause harm to people.

Third, the whole concept of risk tiering is actually a concept of a two-phase risk assessment. In the first phase, if the organism being genetically modified is a well-characterised plant, then it will automatically go into a lower level of risk assessment. Consequently, before the actual risk assessment is undertaken, *ipso facto*, a risk assessment has not only already been undertaken and the results announced as being low risk, but in addition, the risk assessment has been based on assumptions of low risk instead of measured evidence of risk as would occur in a proper risk assessment.

Each risk assessment should be done on a case-by-case basis and on the basis of evidence rather than a assumptions. Tiering should never be used.

Furthermore, safety assessments should be done to the standards described in the answer to the question: "What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?"

What examples exist of licence applications to the Regulator that could be 'fast-tracked' under a risk tiering system, with evidence of scientific and technical integrity that the aims of the Scheme (protection of human health and the environment) will be delivered?

Tiering is scientifically unjustified, and rather than protecting human health and the environment, will likely increase risks to human health and the environment. Please see above for reasoning.

Under a regulatory framework to tier risk for environmental release, what efficiencies might be delivered to regulated stakeholders?

The Public Health Association of Australia (PHAA) is the principle non-government organisation for public health in Australia. As such, our concern is the health of Australians rather than efficiencies that may or may not be delivered to regulated stakeholders. Furthermore, according to the Review of the National Technology Scheme's Consultation Paper, the scheme has a "broad focus on protecting the health and safety of people and protecting the environment", and that "the objective of the GT Act is to protect the health and safety of people, and to protect the environment". Consequently, it is our view those matters should be prioritised over delivering efficiencies to stakeholders.

How could efficiency gains to the Regulator be quantified?

The concern of the PHAA lies with the health of Australians rather than any "efficiency gains" that may or may not be delivered to the Regulator. Furthermore, according to the Review of the National Technology Scheme's Consultation Paper, the scheme has a "broad focus on protecting the health and safety of people and protecting the environment", and that "the objective of the GT Act is to protect the health and safety of people, and to protect the environment". Consequently, it is our view those matters should be prioritised over efficiency gains to the Regulator and how they may be quantified.

The Review is exploring whether a distinction can be made between classes of organisms so the necessary controls can be applied to the highest risks, rather than applying a one size fits all approach. What justification is there to regulate animals, plants or microbes differently?

It is clear from the Review of the National Technology Scheme's Consultation Paper that this is another example of tiering, that is, this is a proposal that "plants with a long story of commercialised release" should be subject to a less rigorous form of risk assessment than other GMOs. Such an approach is scientifically unjustified. Please see our earlier reply to "What support exists for a regulatory framework providing for tiered risk?"

All genetically modified animals, plants, insects, fish, microbes etc. should be subjected to a rigorous risk assessment. There should be no pre-emption, no assumption, that it is less risky to apply a particular genetic modification technique on one species, genus, family, order, class, phylum, kingdom or domain compared to another. In contrast, there is evidence that these new GM techniques cause unprecedented on-target and off-target genetic modifications to a variety of organisms that they have been applied to.

In what way might different applications be treated differently (e.g. medical, agricultural, industrial, environmental, etc.)?

Different applications are already treated differently. For example, agricultural crops that are grown in Australia are regulated by the OGTR, while those that are imported into Australia in the form of food are regulated by FSANZ. Medical applications developed in Australia are assessed by the OGTR and the Therapeutic Goods Administration (TGA), and if they undergo clinical trials in Australia, they would also need to be assessed by a human ethics committee for the risks and benefits to the participants of the clinical trial. Consequently, different applications are already assessed by the OGTR in partnership with other relevant bodies who bring their own particular experience and expertise for each particular GMO.

Advocates for deregulating the use of these new techniques in areas such as agriculture ignore the fact that it is well understood that when these new techniques are used in medicine, they can result in unexpected and unprecedented genetic modifications. Because of this, these new techniques are heavily regulated for medical applications. To regulate these new techniques in medicine but to deregulate them in areas such as agriculture would be policy double-speak. That is, apparently the techniques are so precise, predictable and safe that they do not need regulation, while at the same time being so imprecise, unpredictable and unsafe that they do require regulation.

How might the Scheme accommodate the DIY-biology movement?

It is clear that kits that allow people to undertake DIY biology in their garage or kitchen are now available. They include[13] kits that promise "Everything you need to make precision genome edits in bacteria at home including Cas9, gRNA and Donor DNA template for an example experiment" for as little as $130. And for $3000, "We will set you up with everything you need to start your own extensive home lab doing molecular biology and genetic engineering. We will guide you through setting it up and we will also provide you with a CRISPR kit and other kits to get you started!" and that "everyone will be able to use these kits (they contain everything you need, no extra equipment is required), even if you have had zero experience with Biotechnology (there will be extensive written protocols and videos available)".

It is also clear the that power of these kits is only likely to increase over time.

If DIY biology is allowed, there will need to be a definition about how large and/or sophisticated a home lab can be before it needs to be regulated. This is because there is the potential for industry or university people to set-up a "home lab" to do what they may call "DIY biology" in order to avoid regulation for making a GMO that would otherwise be regulated. Where does the line get drawn between "DIY biology" that needs regulation and "DIY biology" that does not need regulation? After all, a reasonably large home garage could make a fairly large laboratory, and a group of people could build a large garage, place a lab inside, and call it DIY biology.

Furthermore, it is also clear that DIY biology poses higher risks to heath and the environment than regulated research for several reasons. First, on the whole, a biohacker would be less likely to be fully trained, resulting in a greater likelihood of adverse outcomes being generated. Second, there is no oversight by a "Responsible Person" such as a supervisor or biosafety committee, resulting in a greater likelihood of adverse outcomes being generated. Third, a home laboratory is less likely to be properly equipped, leading to a greater probability of an environmental release of the hacked organism, such as flushing modified organisms down the drain to potentially eventually enter food and water supplies. Fourth, the gene hacker may actually be trying to develop an organism that is designed to have an adverse impact on health or the environment, for example by making a bacterium or virus more lethal as a terrorist weapon.

Consequently, due to the dangers, the Scheme should not "accommodate" DIY genetic engineering at all. All genetic engineering should be regulated by the OGTR who can ensure that genetic engineering is conducted by properly trained people undertaking approved research in a proper laboratory according to appropriate biosafety guidelines. Consequently, DIY biology and the importation and development of such kits should be banned.

What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?

The current scheme is poor at measuring risk and safety. Currently, there is no requirement for animal or human studies in order to make a determination that a GMO is safe for release into the environment or to enter the Australian food supply. Moreover, the quality of any animal studies used to support claims of

safety of GM crops has been highly criticised as being poorly conducted, largely undertaken by vested interests, and lacking in endpoints that are relevant to human health. There is therefore a lack of evidence that GMOs are safe, particularly compared to the standards required of pharmaceutical drugs. It is therefore recommended that regulation of GMOs to enter the food supply be aligned with the much better standards of the European Union, which now requires 90 day sub-chronic rat toxicology studies to be undertaken for GMOs that are to enter their food supply. We further recommend longer, chronic animal studies to better reflect the Australian population's exposure to GMOs. It is further recommended that those rat studies actually meet OECD guidelines and that animal testing be required to assess all four major areas of concern, being allergies, reproductive outcomes, toxicology and cancer. If the GMO passes these tests, it should be further tested in basic human trials before release. This is particularly the case for GMOs that will enter the Australian food supply, because 24 million Australians would then likely be exposed to the GMO and to any adverse effects from that GMO.

This type of procedure is common for other substances (e.g. pharmaceutical drugs) and procedures (e.g. surgical procedures) as a result of problems in the past when they were claimed to be safe and efficacious, but were later found to cause harm. It is regarded as the gold standard of how to assess safety. It is a step-by-step process where each step is concluded and assessed before the next step is undertaken. If a substance or procedure fails a step, the process stops. First, animal studies are conducted to determine benefits and harms. Then the four phases of human clinical trials are conducted, where Phase I looks at harm in a small number of volunteers, Phase II looks at benefits in a small number of volunteers, Phase III studies benefits and harms in a much larger number of people using a double-blind randomised controlled trial, and then the substance is monitored in the community (Phase IV). More conservative epidemiologists still do not regard a substance or procedure to be safe and efficacious until several Phase III clinical evaluations have been conducted by different research groups and the results pooled using a Cochrane review meta-analysis. [14]

Even then, there are numerous examples of evidence of harm being found only during Phase IV of the process, i.e. after the substance or procedure had passed clinical trials, had obtained regulatory approval and was being monitored in the community. Vioxx (also known as rofecoxib), an anti-inflammatory drug, is one example. By the time independent researchers had concluded that it caused harm and the drug was withdrawn from sale against the wishes of the manufacturer, it was estimated to have caused 139,000 heart attacks and killed 26,000 people.[15]

Public health professionals have repeatedly seen this kind of outcome. Consequently, to a public health professional, because no organism made using these new techniques appears to have gone through Phases I, II and III of human clinical trials, these organisms cannot be considered to be safe for human health. For the same reason, neither can previous versions of GM foods.

Once a substance is released into the food supply or the environment, epidemiological studies such as cohort or case-controlled studies are required to determine if they cause harm in the population. These studies compare the health outcomes of people exposed to a substance, to those who are not exposed. There are thousands of examples of where these studies have been used, including numerous examples investigating the effects of infectious diseases, tobacco, alcohol, asbestos and heavy metals such as lead (e.g. the Port Pirie study, leaded petrol) and mercury (e.g. Minamata disease) on health.

In order to do this type of study, it is important to be able to identify those who are exposed and those who are not exposed. If these new GM techniques are assumed to be safe and hence do not need to be regulated, then these GMOs will likely appear in the environment and in the food supply in a way that may make it almost impossible to determine who is exposed and who is not, thereby making it almost impossible to properly undertake epidemiological studies into their effects in the population. For example, the effects of eating these new GMOs couldn't be properly elucidated if it could not be determined who

had been eating them because foods from these organisms were not labelled. If, as a result of the current Review, a decision is made that organisms made using these new techniques are not GMOs, then they will not be labelled. Given that these new techniques are very recent and their long-term effects are unknown, this would be a profoundly unwise step. That is, it would be profoundly unwise to, at this stage, through a lack of regulatory oversight, approve a process that would prevent later epidemiological studies into the health effects of these new organisms.

It should be noted that the health and financial burden will be high even if only a small proportion of the population is affected by ill-health. Based on the current population of Australia being 24 million, if a GMO made using one of these new techniques caused only 1 in 1,000 people to get ill, then 24,000 people would be ill in Australia, with the cost being picked-up by Australian State and Commonwealth governments. Consequently, of these two burdens, it is clearly preferable to err on the side of a regulatory burden rather than a health burden.

What opportunities are there for principles-based regulation in the Gene Technology Scheme? What advantages could be gained from doing this? What drawbacks are there from such an approach to regulation?

Principles-based regulation appears to be a method of setting principles for GMO developers to adhere to rather than a set of rules. It therefore puts the subsequent setting of rules into the hands of GMO developers. It is a "trust me" form of deregulation, whereby a principle is established that all can agree on, such as when developing a GM crop, to develop a safe GM crop, but where the developer of that crop then determines what is "safe".

An example of how this would work for road traffic laws would be to instruct road users to "drive safely" and to leave it up to the driver as to what that meant. However, evidence shows that some drivers regard "safe" driving to be driving while drunk, driving through red lights and speeding. If a principles-based regulatory system was used for driving, then regulators of driver behaviour such as the police would need to argue the point in court over whether a particular driver had breached the "drive safely" principle or not for each and every driver. The courts would be bogged-down with drivers, injury specialists and police arguing over every potential breach as to whether the driver had been driving safely or not. Because of the chaos that would result, we have instead installed a rules-based system that clearly states that the following are illegal: driving with a blood alcohol reading over 0.05%, driving through a red light and driving above the speed limit for that area. Moreover, we have clearly sign-posted the speed limit for different areas of roads, such as school crossings.

Similar to the road safety example above, if a principles-based regulatory system was instituted in Australia and the OGTR (or some other body) decided that a large multi-national GM company had breached a principle, and the company disagreed with that opinion, the situation may need to be resolved by arguments in court over whether the principle had indeed been breached or not, where the resources of the complainant would be pitted against all the legal and financial resources available to the large multi-national company.

As a result, a principles-based regulatory system should not be used for gene technology. Rather, the OGTR should determine clear rules for GM developers to follow.

Are there any non-science aspects that would enhance the object of regulation, that do not place unnecessary burdens on the regulated community? How might these be considered?

The answer to this question is covered elsewhere in this submission and include labelling foods containing GMOs in order to give consumers choice and to allow for epidemiological investigations, and to continue to allow States to enact moratoria on growing GM crops.

In addition, at present, farmers who choose not to grow GM crops for marketing or other reasons take a financial loss if a neighbouring famer grows a GM crop in a way that the crop trespasses onto the non-GM-farmer's land, contaminating his crop. Such farmers should be protected via a strict liability scheme, where they can be compensated for GMO trespass, as it is clear from the Baxter v. March legal case that current legal channels are inadequate to compensate an affected farmer for his losses.

The Review is exploring the practical implications to the Scheme of harmonizing Australian regulation with the regulatory needs of trade partners. What are the potential impacts on market access for exporters of animal and plant derived food products?

The Review of the National Gene Technology Scheme Consultation Paper suggests that GM crops provide "improved crop cultivars" at a time when "productivity growth across Australian agriculture has plateaued over the past twenty years", thereby implying that GM crops increase yields and are needed to boost productivity in Australia. It should be noted that the last twenty years has also seen reduced funding for traditional plant breeding and increased funding for GM crop breeding. Moreover, a review of crop yields since the introduction of GM crops has seen no difference between the crop yields of the USA (a major up-taker of GM crops) and Europe (which grows almost no GM crops) (Heinemann et al., 2014).[16]

The potential impacts on market access for exporters depends on how other countries decide to regulate these new GM techniques for animal- and plant-derived food products. Some countries have already determined that organisms made using these new techniques are GM and other countries have decided that they are not. Many countries have yet to make a determination, but as reviews commissioned by the Austrian and Norwegian governments have concluded that there is insufficient knowledge about the risks of these new techniques, and that products derived from them should undergo a comprehensive case-by-case risk assessment, [17] it is likely that the EU will regulate these new techniques. Therefore, it is likely that there will be a patchwork of different regulatory requirements globally, with some of Australia's trading partners having regulatory requirements and not others.

Therefore, while some commentators have suggested that regulating these new organisms in Australia could lead to trade restrictions for Australia, it is also true that exempting these organisms from regulation could also lead to trade restrictions when Australia exports to countries that require these organisms to be regulated and labelled.

Of greater importance, however, as the recent OGTR Discussion Document has noted of our closest trading partner: "New Zealand has recently amended its legislation to clarify that techniques developed after 1998, including genome editing, are within the scope of regulation as GMOs". Consequently, the New Zealand Government has, by definition, determined that these new techniques are GM.

As Food Standards Australia New Zealand (FSANZ) sets food standards for New Zealand as well as Australia, a determination by the Australian government that these new techniques are not GM could put FSANZ in a difficult position.

A decision that these new GM techniques produce GMOs, as well as a decision by this review that these processes and products will be regulated, will allow Australia to export products anywhere in the world by providing quality assurance to importers of our products. In contrast, a decision to deregulate them will likely result in considerable difficulties in segregating them from other crops, in traceability and being able to assure countries importing our products that they are free of GM contamination. Australia could then be in the unfortunate situation of the USA, where repeated GM contamination of their exported grains has resulted in blocked imports (particularly by Australia's largest trading partner, China), national and international legal action, and losses and compensation pay-outs of many millions of dollars.

Consequently, the OGTR should regulate organisms made using these new techniques. Furthermore, there should be a requirement for developers to produce a test to detect the GMO produced, and for the test to

be provided to exporters at minimal cost, so that exporters can test their goods, in order to reassure importing countries that Australia's products meet the importing country's GM requirements. That test can also be applied to products sold in Australia to assist food producers here to properly label their goods for GM content for Australian consumers.

Theme 3 – Governance issues

What will reassure the Australian public and regulated communities of the integrity of the Scheme?

There is currently little trust in the Scheme by the public and the PHAA. The means of reassuring the Australian public about the integrity of the Scheme are discussed under "What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?" and "What does the public need in order to accept the increasing availability and range of use of gene technologies?".

What mechanisms could address the challenges that making changes in the Scheme might entail: Domestically – across a federated government system experiencing different political agendas and community sentiments? Internationally – relating to other agreements, trade agreements, and harmonised regulatory approaches?

For community sentiments, please see the reply to "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below.

For State-related issues, please note the importance, stated below, of States being allowed to maintain their right to declare a moratorium if their economic modelling shows an advantage in doing so.

For trade issues, please see the replies under other questions about trade issues.

For harmonised regulatory approaches, please see the reply to "The Review is exploring the practical implications to the Scheme of harmonizing Australian regulation with the regulatory needs of trade partners. What are the potential impacts on market access for exporters of animal and plant derived food products?"

Please also note that the Object the Gene Technology Scheme is to protect the environment and the health and safety of people.

The Review is exploring how to ensure the rate of adaptation of the Scheme keeps pace with changes in technology and community values. What principles should guide the level at which a decision is made within the Scheme?

For the principles related to community values, please see the reply to "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below.

As changes in technology occur, there is a tendency for the proponents of the technology to be enthusiastic about the change and hence to over-estimate the benefits and underestimate the risks. Such proponents tend to be heavily represented on bodies such as the GTSC, the GTTAC and Institutional Biosafety Committees. There is therefore a risk for regulators to get caught-up in the enthusiasm and do likewise. There is therefore a need to have some oversight of these groups, such as reviewing the Scheme every five years and utilising the Forum.

Does reviewing the Scheme every 5 years best address the needs of the Scheme? Is there a preferable option?

A review every five years is appropriate.

Is the existing role of the Forum the most suitable way of providing oversight and guidance for the Scheme?

Yes.

What criteria should be used to determine what legislative amendments are minor and could be progressed without going to the Forum?

Altering the process in this suggested manner could be regarded as watering-down current requirements and hence a form of deregulation, something which is considered to be contrary to the Object of the Gene Technology Act, being to protect the environment and the health and safety of people. In addition, who will determine what is sufficiently "minor" to able to follow this path? The Forum is the appropriate place to discuss legislative and regulatory changes, not only for these reasons but also to ensure that the process is transparent and inclusive. Questions elsewhere in this Consultation make it clear that the community currently lacks confidence in the gene technology regulatory scheme. Making the process less transparent and inclusive is only likely to make that situation worse.

GM moratoria remain a debated element of the Scheme and the Review is seeking to understand the factors and practical implications for all stakeholders. What evidence is there to support economic and trade advantages of GM moratoria – or indeed, the absence of GM moratoria?

The current debate over growing and harvesting GM crops in Australia centres around GM canola. At the latest-available figures in December of 2017, non-GM canola was providing a premium to growers of $27-$35/tonne in WA, up to $47/tonne in Vic and up to $59 in NSW. Given that the costs for farmers growing non-GM canola also tends to be less, because for example, the seeds tend to cost less and there is no GM technology fee, non-GM growers tend to make a higher profit than GM growers. South Australia and Tasmania currently have a moratorium on the growing of GM crops for commercial purposes, due to the marketing and trade advantages of being able to declare all grains produced in the State to be free of GM contamination. The advantages of the moratorium to SA were such that the SA government recently extended its moratorium until 2025. Consequently, States should be allowed to maintain their right to declare a moratorium if their economic modelling shows an advantage in doing so.

How could regulated stakeholders access the benefits of a national scheme, whilst ensuring jurisdictions are able to effectively trade in the international context?

Regulated stakeholders can do this already. States should be allowed to maintain their right to declare a moratorium if their economic modelling shows an advantage in doing so.

What other mechanisms could be utilised in order to realise the outcomes currently achieved through moratoria?

The State of SA recently extended its moratorium, indicating that it saw a moratorium to be the best mechanism to obtain the marketing and trade advantages of being able to declare all grains produced in the State to be free of GM contamination. States should be allowed to maintain their right to declare a moratorium if their economic modelling shows an advantage in doing so.

The Review is exploring how the Scheme can harness the emerging benefits of gene technology that were not anticipated at the establishment of the Scheme. Are existing mechanisms, when used effectively, sufficient to ensure the emerging health, environmental and manufacturing benefits of gene technology that were not anticipated at the establishment of the Scheme, can be harnessed for Australians?

The PHAA is aware of a long history in other areas, such as for pharmaceutical drugs and medical devices, where independent researchers failed to find the benefits claimed by developers, and often found adverse effects that the developer failed to find or ignored, which then eventuated in the drug or device being

removed from the market, but only after it had caused harm. Consequently, we would urge caution about any claim by a developer of a GMO of any health, environmental or manufacturing benefits of a GMO. All such claims should be verified by researchers independent of vested interests. However, determining the truth about any claim made about the product is particularly problematic at the time that such a product is given to a regulator for regulation, because the product is often under patent protection, so that independent researchers cannot obtain the product for research purposes to verify any claims. We would therefore urge the Scheme to have a mechanism of allowing independent researchers to access GMOs for independent research, as described elsewhere in this submission.

Should other policy principles be developed that are tailored to horizon technology management?

As changes in technology occur, there is a tendency for the proponents of the technology to be enthusiastic about the change and hence to over-estimate the benefits and underestimate the risks. Such proponents tend to be heavily represented on bodies such as the GTSC, the GTTAC and Institutional Biosafety Committees. There is therefore a risk for regulators to get caught-up in the enthusiasm and do likewise.

There is therefore the need for the Precautionary Principle to be fully applied and for a policy to be enacted that all risk assessments need to be fully completed and completely evidence-based with no room for assumption-based reasoning. That is, there is a need for risks to be based on experimental evidence, where experiments have not only been performed and fully analysed, but all the raw data have been given to the regulator, and the regulator has done proper due diligence by re-analysing the raw data to ensure that what the developer has said is true. If experimental evidence is not available, then the regulator should not assess the GMO to be safe for health and/or the environment. As an example of this, in its decision to allow the commercial release of GM InVigor canola into the Australian landscape, the OGTR decided that the release would cause no risk to Australian native birds, animals and insects on the basis of no scientific studies into the matter. Furthermore, for dsRNA technology, both the OGTR and FSANZ have been criticised, not only for making assumptions that dsRNA technology is safe and hence not requiring regulation, but for making assumptions that are at odds with experimental evidence (Heinemann et al., 2013).[18] The corollary to this is that any policy that the technology is safe until it is proven to unsafe, should be overturned.

There should also be a principle that all of the new GM techniques will result in a GMO, and that GMO should be assessed for health and environmental risks by the regulator before it is released into the environment or the food supply. This includes dsRNA technology.

Furthermore, there should not be a policy, a belief, that the only new substances that are likely to be found in GM crops are the new substances that have been genetically engineered to appear and that no other substances could be produced and hence do not need to be looked-for and assessed.

“Null segregants (offspring of GMOs that have not inherited the genetic modification or a trait from genetic modification) should be regarded as GMOs because it cannot be assumed that there have been no changes in genetic material or genetic expression elsewhere in the organism unless both matters are thoroughly checked. Therefore, these organisms should be regulated as GMOs.

All new GMOs need to be fully safety assessed by aligned with the much better standards of the European Union, which now requires 90 day sub-chronic rat toxicology studies to be undertaken for GMOs that are to enter their food supply. We further recommend longer, chronic studies to better reflect the Australian population’s exposure to GMOs. It is further recommended that those rat studies actually meet OECD guidelines and that animal testing be required to assess all four major areas of concern, being allergies, reproductive outcomes, toxicology and cancer. If the GMO passes these tests, it should be further tested in basic human trials before release. This is particularly the case for GMOs that will enter the Australian food supply, because 24 million Australians would then likely be exposed to the GMO and to any adverse effects

from that GMO. For more information, see the reply to the question: "What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?"

A Health Impact Assessment (HIA) of any deregulation of these new techniques should be conducted to determine the latter cost. According to the CDC (Centres for Disease Control and Prevention) of the USA, a HIA "brings together scientific data, public health expertise, and stakeholder input to identify the potential health effects of a proposed policy, plan, program, or project. An HIA offers practical recommendations for ways to minimize risks and capitalize on opportunities to improve health."[19]

The OGTR's definition of the environment should be reviewed to one that aligns with public values. To the OGTR, "the environment" seems to be just natural, undisturbed ecosystems, of which there is very little remaining in Australia. The rest of Australia, including agricultural lands, disturbed lands, roadside verges and people's backyards, do not seem to be included in the definition, despite being parts of the Australian environment.

What other factors could be considered in the regulatory decision?

Please see above.

What data sets are required to assist the regulator to consider benefits in addition to the risks?

All experimental data from the developer of the GMO supporting risks and benefits should be given to the regulator and the regulator should place that on their website at the time that an application is made to a government regulator. It should be required that the regulator does due diligence and re-analyse the data so that the regulator can be assured that the data supports the developer's claims. Experimental data from independent researchers should also be obtained to verify any claims made by vested interests about the touted benefits of their products. The experience of other commercial, health-related areas, such as pharmaceutical drugs, show that data from independent researchers tends to be more accurate than those from vested interests and tends to show fewer benefits.

The Review seeks to identify areas where clear policy positions could enhance the Scheme and support compliance with regulation. What aspects of gene technology would benefit from greater policy position clarity?

A definition of a GMO should be extended to all organisms made using the new techniques. These organisms should then undergo a full safety assessment, as described in the reply to: "What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment?".

The safety and environmental impact of a GM crop that is genetically engineered to be resistant to a herbicide should include the effects of the expected use of the herbicide.

What other mechanisms would provide suitable policy clarity that would enhance the Scheme and support compliance?

Please see above.

The Review is seeking to identify any regulation gaps and overlaps at the interface of the Scheme and other product regulators. What are the pressure points at the boundaries between regulatory schemes that are caused by regulatory gaps or overlaps?

There appear to be different definitions of what constitutes a GMO and "the environment" between regulators, which should be addressed.

How can existing coordination functions be utilised more effectively to support the Scheme to be agile and facilitate transitions across regulatory framework boundaries?

The OGTR should be the lead regulator in any process of regulating GMOs, and the umbrella under which other regulatory bodies would sit.

What other activities would enhance this?

Please see above.

What amendments to the funding model would support an agile Scheme that will cope with increased future activity?

While any funding that results from a "user pays" model appears beneficial to a government, because it reduces the cost to the government, it can also lead to a public perception that, by providing funds to a government to provide a service (a safety or environmental assessment), the GM company is employing staff (however indirectly) in a government department to undertake a service for the GM company, and that therefore, an employer/employee relationship may have been established where the GM company is the employer and the government staff are the employees of the company. Consequently, in order for the public to trust the GM regulatory process, there should be no company funding of the regulatory process. Instead, the government should adequately fund the OGTR to undertake assessments of GMOs in the public interest.

How could some aspects of the Scheme be funded through other mechanisms that will support innovation and competition in gene technology, whilst retaining public confidence in the Scheme?

Worryingly, this question about how innovation and competition in gene technology could be supported is not a neutral question and could be reasonably interpreted as asking: how can we promote GM?, Questions such as this reduce the public's confidence in the Review process, as it appears that the Review does not wish to be unbiased, but rather wishes to promote GMOs. It should be remembered that the Object of the Gene Technology Act is to protect the environment and the health and safety of people, not support innovation and competition in gene technology.

Theme 4 – Social and Ethical Issues

How do we help the community to best understand the benefits and risks of a complex, science-based technology?

Please see the answer to: "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below.

Where does the community have confidence in the gene technology regulatory scheme? How can this be maintained?

Please see the answer to: "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below.

Where is there a lack of community confidence in the gene technology regulatory scheme? Why might this be, and how can confidence be built?

Please see the answer to: "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below.

What does the public need to know?

Please see the answer to: "What does the public need in order to accept the increasing availability and range of use of gene technologies?", below.

Who is best placed to provide that information?

Independent scientist who have no vested interests in making or promoting GMOs. Note that since the CSIRO makes and commercialises GMOs, it has a vested interest in GMOs.

The Review is seeking to better understand how to balance consumer choice within the scope of the Scheme. What does the public need in order to accept the increasing availability and range of use of gene technologies?

There seems to be an undercurrent to the questions in this section along these lines of: how do we get the public to like GMOs more, how do we promote them; and a view that if only the public were not so ignorant about GMOs, they would appreciate them more and be happy to consume/use them, so how can we make them less ignorant? Unfortunately, evidence indicates that the more that the public knows about GMOs, the less they like them. It should be noted that people are not ignorant about risk/benefit analyses, since most undertake them daily in their personal lives. They also tend to understand the difference between the risk/benefit profile of a GM technique used in medicine and one used in food. In medicine, there is an understanding that the person undergoing the treatment takes a risk in order to have a potential benefit, such as saving their life. For example, people will undertake the risks of chemotherapy in order to try to extend their life if they are given a diagnosis of cancer, but would not otherwise voluntarily undergo chemotherapy. In contrast, for GMOs used in food, people understand that current GM crops have no benefit to them personally and may have a risk to them personally, and that therefore, there is no benefit to counterbalance the risk to them.

The public therefore needs to treated with the respect due to them, as a result of understanding that people make daily risk/benefit decisions. The amount of hype put out by the industry does not help; apparently, GMOs will cure all the world's ills, whether there is any evidence for a particular application or not. Or as one person described the hype: "GM is the answer! Now, what was the question?"

Sandman's model of how the community measures risk is well known and is pertinent here. Essentially, the community measures risk by looking at the hazard plus the outrage they feel about the matter. Outrage is increased if exposure is coerced, exposure is felt to be unfair, if the hazard is controlled by others and the process around the hazard is unresponsive. All of these factors are in play with GMOs. For example, if GMOs are not labelled in the food supply, then people will have no choice as to whether they eat them or not, which will leave them with the feeling that their exposure is coerced and unfair. Furthermore, since the public has asked for full labelling, if that does not happen, then the public will feel that the hazard is being controlled by others and the process is being unresponsive. Hence it is likely that if the Scheme follows its current path that outrage and hence resistance to GMOs will increase. In contrast, these factors tend NOT to be in play when it comes to the use of GM technologies in medicine, where the person gives informed consent – the patient is given facts about the risks and benefits of the procedure, given advice about what the doctor thinks the patient should do, and then the decision rests with the patient about whether to undergo the treatment or not.

Consequently, the public needs to be given facts, not hype, about the risks and benefits of each GMO so that each person can provide informed consent when determining how much of the technology they wish to take-up in different areas of their lives.

If you want to increase the public's trust in the Scheme, then all GMOs need to be fully safety assessed (as described in the answer to: "What measures might be warranted to identify potential long-term or 'down-stream' effects of gene technologies on humans and the environment", all GMOs need to be regulated (including some of those that the OGTR is currently considering deregulating, such as dsRNA technology) and all GMOs need to be labelled (including all those that are currently exempt). Furthermore, labelling

needs to be policed so that the public has trust that the label honestly reflects the ingredients in the food. If these steps are not done, outrage will not only continue, but likely increase.

A further increase in the public's trust of the scheme would be to increase the transparency of the regulatory and safety assessment process by requiring all raw data that is provided to the regulator by the GM company to be placed on the regulator's website at the time the application is received, so that independent health and environmental researchers may also analyse the data. This is often required for pharmaceutical drugs and has resulted in greater safety for the public, e.g. with the drug Vioxx.[20]

An additional increase in the public's trust would be to provide public funding to independent investigators to investigate the health and environmental impacts of GM crops via e.g. ARC and NHMRC grants, with the results published in the peer-reviewed literature. In this way, the public could be told that independent researchers are actively looking for any harms.

The public tends to feel much more reassured about their safety if they can "see a police presence". For GMOs, this means not only labelling all GMOs in the food supply, but also having the labelling policed in an obvious manner, with those breaking the labelling laws being "punished", such as being fined. Allowing independent researchers access to raw data on the regulator's website would be another form of policing and having a surveillance system would be another.

What does the public need in order to determine whether to provide social licence for the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector?

Please see the answer to: "What does the public need in order to accept the increasing availability and range of use of gene technologies?", above.

What are the ethical considerations for enabling access to medical treatments?

"Treatments" may occur via a clinical trial into the efficacy of a new treatment or via treatments offered by treating doctors. There is a well-established procedure of how treatments should be provided via a clinical trial, using the methodology of pharmaceutical drug trials. The procedure includes obtaining permission from a human ethics committee of a University, which also has oversight over the trial. This process gives rights to the volunteer such as the need for informed consent, the use of Clear-English information sheets to the volunteer, and the right of the volunteer to leave the trial at any time. Similarly, treatments provided to patients by doctors also require the patient to give informed consent, that is, the patient is given facts about the risks and benefits of the procedure, given advice about what the doctor thinks the patient should do, and then the decision rests with the patient about whether to undergo the treatment or not. Therefore, if current, well-established procedures are followed, there should be manageable risks to the patient or volunteer.

However, there may also be risks to the community or to the environment from such treatments that fall outside of what has been described immediately above. Matters such as these need particular care in their assessment: off-target effects to the genome of the person undergoing the treatment, the stability of the genetic alteration in the person, whether the genetic change can be inherited, whether the genetic change can act as a gene drive etc. These would be assessed by the OGTR.

The Review is seeking to explore and better understand factors relating to choice and the potential impacts on trade, alternate farming techniques and the broader environment. How do we ensure that information is available to the community on the value of GM and what it can do? Who is responsible for providing this and why?

Worryingly, the question: "How do we ensure that information is available to the community on the value of GM and what it can do?" is not a neutral question and could be reasonably interpreted as asking: how do we promote the benefits of GM?, particularly as the following was not also asked: "How do we ensure that

information is available to the community on the risks of GM and what it can do about them? Who is responsible for providing this and why?" There is therefore concern that the question, as asked, is biased and hence will generate bias in the answers. Questions such as this reduce the public's confidence in the Review process, as it appears that the Review does not wish to be unbiased, but rather wishes to promote GMOs.

When it comes to better understanding the potential impacts on farming, there is a need for farmers to make an informed choice about whether to use the technology or not. Therefore, there is a need for farmers to be able to discuss the issue with other farmers who have used the technology about their experiences. Yet it is our understanding that the legal agreement that farmers need to sign in order to be able to grow a GM crop includes signing a gag clause that prevents them from speaking about how well the GM crop performed. Consequently, only farmers who are chosen by GM crop companies are given permission to speak, resulting in biased advice to other farmers. It should be made a condition of any commercial release of any GMO that there will be no such gag clauses and that those who use the GMO can freely discuss their experiences, including how well or not a GM crop yielded, how much it cost to grow and how much profit the farmer made compared to a non-GM crop.

Furthermore, it is our understanding that the agreement that a farmer signs in order to grow a GM crop makes him liable for any GM contamination that results, even if the farmer adheres completely to the conditions in his Technology User Agreement. In the interests of making an informed decision, this should also be made clear to farmers.

In addition, it is important that farmers are made aware of the location of any field trials of GM crops in their vicinity so that they can better monitor their crops for GM contamination.

Great care needs to be taken with considering thresholds for Low Level Presence (LLP). It should be remembered that for many countries, including the EU, that allow some LLP, there is an allowance for a small amount of **unintended** contamination of a GMO in an otherwise non-GM product. However, when the contamination is known to be present, or there is a repetition of contamination, or the contamination could reasonable be known to be present, then then the contamination is no longer **unintended**, but is rather is considered to be **intended**. Therefore an allowance for a threshold of LLP is likely to result in Australian exports being rejected from certain countries.

Is the Scheme putting up barriers to research and development and commercialisation of agricultural applications?

While entities that wish to quickly commercialise their GMOs may argue that regulation is somehow a "barrier" to them, it is important to allow regulators the time to be able to properly determine the risks of a GMO in order to ensure that their responsibilities under the Gene Technology Act are met, specifically that the GMO will not cause harm to the environment or to health. It should be remembered that if the regulatory process is hastened so that any harms are not picked-up during the regulatory process, and the GMO is commercialised, and the GMO causes harm to health or the environment, that it will be Australian and State governments who will be paying for any healthcare or environmental remediation that will be required. And some of those costs are only likely to be refunded to governments once legal action is concluded, and only if that legal action is successful. It is consequently in governments' best interests to ensure that the Federal Government undertakes a rigorous safety and environmental assessment of any GMO before commercial release.

However, it should also be said that the current system does have an inbuilt barrier to research – because the raw data from those who wish to commercialise a GMO is not placed on a website for all to see, there is an insurmountable barrier for public health and environmental researchers to be able to analyse and assess the data. It should be remembered that such public scrutiny of company data is often required for

pharmaceutical drugs, and it was only after independent researchers analysed such company data on the drug Vioxx, that harm was found.

It should also be noted that the Technology User Agreements that farmers need to sign generally contain a clause that prevents them from doing any research on the crop, such as comparing yields between the GM crop and a non-GM crop, and also prohibits them from selling or giving the grain to researchers who wish to undertake health or environmental research. This severely impedes research into the safety of GMOs by restricting safety assessments to only those researchers who have been approved by the GM company, leading to a potential bias towards reporting findings that are favourable to the industry and avoiding the reporting of adverse findings. The Scheme should provide a means of allowing such research on the GMO, so that anyone who wishes to test the GMO for agronomic performance, health and environmental outcomes to have free an unfettered access to the GMO. This should be made a condition of any commercialisation of the GMO.

Conclusion

The PHAA welcomes the opportunity to provide input to the 2017 Review of the National Gene Technology Regulatory Scheme Consultation Paper. The PHAA is the principal non-government organisation for public health in Australia with approx. 1900 members representing over 40 professional groups and an evidence-based policy on GM foods. The PHAA has drawn heavily upon that policy to write this submission.

The PHAA would like to particularly highlight the following points:

- Food regulation should aim to protect public health and provide information to consumers.
- It is more important to protect public health than promote commercialisation.
- The precautionary principle should be applied to GMOs.
- These new techniques are in their infancy and are constantly evolving. There is uncertainty and debate about how these new techniques actually work. Consequently, any decision that is made now about the safety of these new techniques is based on opinion, assumption and conjecture, rather than evidence. The new techniques are imprecise, can cause unpredictable outcomes and need thorough safety assessments. They result in organisms that are GMOs. For all these reasons, the techniques and the GMOs that they produce should be regulated. DIY kits should also be regulated. dsRNA techniques should be regulated according to recommendations made in Heinemann et al (2013).
- GMOs should be made freely-available to any researcher researching agronomic, environmental or health aspects of a GMO.
- All safety data generated by a GM company should be given to government regulators, those regulators should be required to analyse it, and the data should be made freely available on-line to all interested independent researchers.
- The majority of the members of the GTTAC of the OGTR should consist of people who are experts in determining the effects of a GMO on health and the environment, and independent of vested interests.
- Government regulators should use thorough, independent experimental evidence in assessments rather than assumptions. These new organisms should not be considered safe until they have undergone long-term animal safety assessments that follow OECD Guidelines, utilizing endpoints

relevant to human health and conducted by independent researchers. These studies should be followed by limited testing on people if the GMO is destined for human consumption.

- A monitoring and surveillance system should be instigated to track the effects of GMOs.
- A Health Impact Assessment (HIA) by a health economist into the consequences of any deregulation of these new GM techniques should be conducted to determine the true costs of any deregulation.
- GMOs made using existing and future techniques should be labelled in order for them to be traced, monitored and to allow for epidemiological studies into them. Labelling also allows for regulatory oversight and allows for consumer choice which maintains trust in the food supply.
- States' rights to place a moratorium on the commercial release of GMO into the environment should remain and be strengthened.
- Regulating the technology does not mean that Australia will suffer from trade disruptions. Rather, Australia will then be in general agreement with the laws of New Zealand. FSANZ regulates food for both Australia and New Zealand and different definitions of what constitutes a GMO between those two countries would put it in a difficult position.
- The Commonwealth Government should allocate funding for independent research into the health and environmental impacts of GMOs.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

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